



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 3, 2014

OssDsign AB
% David Weissburg
Weissburg Associates
808 Williamson St., Suite 402
Madison, WI 53703

Re: K140309
Trade/Device Name: OssDsign Cranioplug
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: September 4, 2014
Received: September 5, 2014

Dear Mr. Weissburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140309

Device Name

OssDsign Cranioplug

Indications for Use (Describe)

OssDsign Cranioplug is intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. It is cleared for use for non-weight bearing applications in adults and adolescents age 12 and older.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

KI40309

1. 510(k) Owner Name and Address:
OssDsign AB
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Sweden
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Email: info@ossdsign.com
Contact: Eva Nicklasson
2. Contact Person:
David Weissburg
Weissburg Associates
808 Williamson St., Suite 402
Madison, Wisconsin, 53703 USA
3. Date prepared: October 3, 2014
4. Trade Name: OssDsign® Cranioplug
5. Regulation Description: Burr Hole Cover
6. Classification Name: Cover, Burr Hole (21 CFR 882.5250, Product Code GXR)
7. Class: 2
8. Predicates:
K120352 Stryker QuikFlap Sterile Procedure Pack (Burr Hole Cover, 14 mm)
K051603 Stryker Injectable Cement
9. Device Description: Cranioplug consists of a titanium (Ti) mesh plate with a biocompatible ceramic. Cranioplug implants are sized to mate with standard 14 mm burr holes common in surgical procedures. Each implant includes the completely formed Ti and fully cured CaP components in one device.
10. Indications for Use: OssDsign Cranioplug is intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. It is cleared for use for non-weight bearing applications in adults and adolescents age 12 and older.
11. Comparison to predicates: The intended uses of the OssDsign Cranioplug and its predicates are the same. All the devices utilize either titanium mesh or calciumphosphate ceramic. Labeling and materials used are equivalent, except that the calciumphosphate ceramic component of Cranioplug is molded and cured before implantation.

	<i>OssDsign Cranioplug</i> , (subject device)	Stryker QuikFlap, predicate comparison A, K120352	Stryker Injectable Cement, predicate comparison B, K051603
Materials	Ti grade 3, proprietary calcium phosphate formulation	Ti grade 2, screws grade 5	Calcium phosphate cement
Titanium thickness	0.5mm	0.4mm	N.A.
Mix/cure	Mixed and cured in manufacturer's facility	N.A	Mixed in the operating room and cured <i>in vivo</i>
Sterility	Sterile	Sterile	Sterile

12. Testing vs. predicates: Cranioplug and its predicates were tested for bench performance characteristics and material composition. Direct comparison of performance, safety and effectiveness of the Cranioplug and its predicates demonstrate that the Cranioplug is substantially equivalent or superior to its predicates in all characteristics. The table below provides a summary of some of the tests completed.

Test	Test Method Summary	Results
Compressive strength	Subject device and Stryker Injectable Cement predicate tested with Universal compression testing machine with 1mm/min. cross-head speed.	Both devices showed compressive strength of approximately 19 MPa.
Falling load	530 g weight dropped on device and predicate installed in anatomical model. Drop height increased until failure.	Subject device and QuikFlap sustained falling loads below 30 cm.
12 hour load	Device and predicate installed in anatomical model. Device placed on pillow and loaded with 7.5 kg weight on opposite side. Plastic deformation measured after 12 hours.	No deformation of subject device or QuikFlap.
Dissolution test	TRIS-buffered solution, pH 7.4 at 37C, 120 rpm shaking table per ISO 10993-14.	Subject device and Stryker Injectable Cement dissolved less than 25 % after 6 weeks.
Cytotoxicity	ISO elution method, ISO 10993-5, extracted in IX MEM at 37°C for 24 hours	No evidence of causing cell lysis or toxicity.
Sensitivity	ISO Subcutaneous Implantation studies – two weeks and six weeks, ISO 10993-6. The test article, sponsor provided control article and the negative control article were subcutaneously implanted in the rabbit.	Classified as a nonirritant as compared to the sponsor provided control article and nonirritant as compared to the negative control article.